Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 12/2024

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:PRAMIPEXOLE HYDROCHLORIDE LA TABLETS 1.5mgMI「OHARA」

Active ingredient: Pramipexole hydrochloride hydrate

Dosage form:white tablet, major axis: 14.1 mm, minor axis: 6.9 mm, thickness: 4.4 mm

Imprint or print on wrapping:プラミペキソール塩酸塩 LA1.5mgMI「オーハラ」, 1 日 1 回, 抗パーキンソン病薬, 湿気に注意, Pramipexole Hydrochloride LA1.5mgMI「OHARA」

Effects of this medicine

This medicine stimulates the dopamine D2 receptor of the brain and improves symptoms (shaking of hands, muscle stiffness, slow movement and inability to maintain posture) of Parkinson's disease.
It is usually used to treat Parkinson's disease.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

・If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have renal disorder which requires dialysis.
・If you are pregnant, possibly pregnant or breastfeeding.
・If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

・Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
・In general, for adults, start with 0.375 mg of active ingredient at a time once a day after meals and then increase to 0.75 mg a day for the second week. Thereafter the daily dose is increased by an increment 0.75 mg at weekly intervals by checking your condition and your maintenance dose is determined [standard daily dose: 1.5 to 4.5 mg]. The dosage may be adjusted according to your age and symptoms, however, the maximum daily dose should not exceed 4.5 mg. This preparation contains 1.5mg of the active ingredient in a tablet. Strictly follow the instructions.
・If you take this medicine as cracked or crushed tablet, the adverse reactions may occur. Swallow the tablet without chewing.
・If you miss a dose, take the missed dose as soon as possible. You should never take two doses at one time.
・If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
・Do not stop taking this medicine unless your doctor instructs you to do so. Especially, if you suddenly reduce the dose or stop the medication, adverse reactions may occur.

Precautions while taking this medicine

・This medicine may cause sudden onset of sleep without warning signs or somnolence and there have been reports of having a car accident during medication. Do not perform dangerous operations such as driving a car, operating machinery or working at heights.
・Avoid drinking alcohol as far as possible since it may intensify the medicinal effect.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include somnolence (semi-consciousness and almost sleeping state), nausea, dizziness, constipation and dry mouth. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

・sudden onset of sleep without warning signs [sudden onset of sleep]
・seeing thing or hearing sound that does not really exist, baseless and subjective thoughts, impaired mind [hallucination, delusion, delirium, confusion, agitation]
・convulsion, consciousness disorder [syndrome of inappropriate secretion of antidiuretic hormone (SIADH)]
・fever, strong muscle stiffness, decreased consciousness [malignant syndrome]

・lassitude, muscle pain, brown urine [rhabdomyolysis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

・Keep out of the reach of children. Store away from direct sunlight, heat and moisture.

・Discard the remainder. Do not store them.If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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